Supreme Court, U.S.
FILED
SEP 27 1985
JOSEPH F. SPANIOL, JR.
CLERK

No. 85-354

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

ORTHO PHARMACEUTICAL CORPORATION,
Petitioner,

v.

CAROLE MACDONALD AND BRUCE MACDONALD,
Respondents.

BRIEF OF RESPONDENTS IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT OF MASSACHUSETTS

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September 27, 1985

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

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QUESTIONS PRESENTED

1. Has the Petitioner timely and properly raised a Federal question so as to give this Court jurisdiction to review the judgment of the Supreme Judicial Court of Massachusetts on a Writ of Certiorari?

2. Does the Petition present any substantial Federal question arising out of the proceedings below which is appropriate for review on Writ of Certiorari?

LIST OF PARTIES TO THE APPEAL IN THE SUPREME JUDICIAL COURT OF THE COMMONWEALTH OF MASSACHUSETTS

The names of all of the parties to the appeal in the Supreme Judicial Court of Massachusetts are contained in the caption to this Petition and are set forth in page ii of the Petition for Certiorari.

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Respondents, Carole MacDonald ("Mrs. MacDonald") and her husband, Bruce MacDonald ("Bruce"), respectfully request that this Court dismiss or, in the alternative, deny the Petition for a Writ of Certiorari of Ortho Pharmaceutical Corporation ("Ortho").

OPINIONS AND JUDGMENTS BELOW

The opinion of the Supreme Judicial Court of Massachusetts and a reiteration of the judgment and proceedings below have been reprinted by Ortho in the Appendix to its Petition, at Pages 1 a through 27 a.

OBJECTIONS TO JURISDICTION

Pursuant to Rule 22.3, the Respondents object to the jurisdiction of this Court to grant the Writ of Certiorari.

Ortho attempts to invoke jurisdiction under 28 U.S.C. § 1257(3), based upon a claim that the lower court judgment deprived it of constitutional rights under the Due Process Clause of the Fourteenth Amendment (Pet. p. 2).

If review of the judgment of a State Court is sought, Rule 21.1(h) of this Court requires that the Petition for Certiorari, in its statement of the case, "specify the stage in the proceedings, both in the court of first instance and in the appellate court, at which the federal questions sought to be reviewed were raised; the method or manner of raising them and the way in which they were passed upon by the court;".

In the litigation here, no Federal question was raised in the Trial Court (Massachusetts Superior Court) or prior to the decision of the Appellate Court (Supreme Judicial Court of Massachusetts).

As conceded in its Petition (p. 6), Ortho first purported to raise its constitutional issue in a Petition for Rehearing to the Appellate Court, which was considered and denied by the Court, without comment (Pet. p. 23a).

This Court has always held that it is a prerequisite to the consideration here of a Federal question coming from a State Court that the question should have been raised in that Court before decision, or that it should have been actually entertained and considered upon a Petition for Rehearing. A mere denial of such a petition by the State Court, without opinion, is not enough. *Tidal Oil Co.* v. *Flanagan*, 263 U.S. 444, 455 (1924); *Rooker* v. *Fidelity Trust Co.*, 261 U.S. 114, 117 (1923).

It is apparent from the record in the proceedings below, that the distinction between oral contraceptives and other

prescription drugs and the scope of regulations of the United States Food and Drug Administration ("FDA") over labelling of such products were put in issue by the briefs and arguments in the lower Appellate Court and Ortho cannot now claim that the ruling of the Court on these issues could not have been anticipated by it in the original hearing.

The record does not establish, affirmatively or by fair implication, whether a resolution of the claimed Federal question was necessary to the Court's determination, or whether its decision was based on adequate and independent state grounds. *Boughton* v. *Exchange Bank*, 104 U.S. 427 (1881).

A party who seeks and is given an opportunity in a State Court to litigate rights claimed by it cannot have the judgment reviewed here on the ground that due process of law was denied, because the litigation did not result successfully. *Remington Paper Co.* v. *Watson*, 173 U.S. 443, 451 (1899).

For the foregoing reasons, it appears that Ortho has failed to establish grounds on which the jurisdiction of this Court may be invoked on Certiorari, and therefore, this Petition ought to be dismissed.

CONSTITUTIONAL PROVISION INVOLVED

The only constitutional provision relied upon by Ortho is U. S. Const. Amend. XIV §1 (Due Process Clause), which is reprinted in the Appendix to its Petition, at page 28 a.

STATEMENT OF THE CASE

This is a products liability action for personal injuries sustained by Mrs. MacDonald and for consequential damages and loss of consortium sustained by her husband,

Bruce, resulting from Mrs. MacDonald's use of birth control pills manufactured by Ortho (R. 10-13).

During the early morning hours of July 24, 1976, Mrs. MacDonald suffered a cerebral vascular accident, otherwise known as a stroke (R. 153). Mrs. MacDonald's stroke was caused by her use of Ortho-Novum, a birth control pill manufactured by Ortho (R. 153-154, 187, 361, 364, 365-366, 392, 393). The stroke caused brain death to about 20 percent of her brain (R. 352). A seizure disorder in turn resulted from the cerebral scar caused by the stroke (R. 159). Mrs. MacDonald was 29 years old at the time of her stroke (R. 156). She is totally and permanently disabled from useful and substantial employment (R. 372).

After a trial in the Superior Court of the Commonwealth of Massachusetts, Worcester County Division, the jury returned a special verdict, finding that Mrs. MacDonald's stroke was caused by an oral contraceptive manufactured by Ortho, that Ortho was negligent and breached its warranty of merchantability in its warnings to Mrs. MacDonald, that Mrs. MacDonald's damages were in the amount of $800,000.00, and that her husband Bruce's damages were in the amount of $50,000.00 for consequential damages and loss of consortium (R. 40-41). The Supreme Judicial Court of Massachusetts affirmed the jury verdict.

Mrs. MacDonald visited a physician in 1973 because she was getting married and wanted to take birth control pills; the physician gave her a prescription (R. 144, 165). At that time, she was given a booklet about the pill (R. 167). The booklet was dated October of 1972 and was entitled "After your doctor prescribes Ortho-Novum" (R. 58, 168). Ortho distributed this booklet for doctors to give to their patients in 1973 (R. 290, 169). These were called "patient information booklets" (R. 92). Carole read the booklet, but it did not say anything about stroke (R. 164). She received no other literature of any type from Ortho concerning the pill (R. 165).

The FDA regulations mandated that a warning by the manufacturer of oral contraceptives be included with the pill packet dispensed to a patient, and that the manufacturer make other written, printed, or graphic materials available to patients (R. 79-81). The regulations also mandated "that information in lay language concerning effectiveness, contra-indications, warnings, precautions, and adverse reactions be incorporated prominently in the beginning of any such materials" (R. 81). Ortho's 1973 patient information booklet did not mention the risk of "stroke" (R. 58-73). However, Ortho changed the booklet in 1978 to include the following warning: "Blood clots (in various blood vessels of the body) are the most common of the serious side effects of oral contraceptives. A clot can result in a stroke (if the clot is in the brain), a heart attack (if the clot is in a blood vessel of the heart) . . .".[1]

Mrs. MacDonald used Ortho-Novum 1/80 birth control pills from 1973 to 1976 (R. 161, 162). During that time, she did not know what "abnormal blood clotting" meant, but did know what "stroke" meant; had she been warned that the pill caused strokes, she would not have used the pill (R. 164).

Ortho's recommended "dosage and administration" of the oral contraceptive prescribed to Mrs. MacDonald was one tablet daily from the 5th through the 25th day of the menstrual cycle, and supplied the pills in various containers, including bottles of 500 tablets (R. 56). Mrs. MacDonald visited the prescribing physician annually, each time receiving a checkup and a prescription for one year's supply of birth control pills (R. 144, 145).

The risk of stroke was 4.1 to 9.5 times greater in oral contraceptive users than in non-users (R. 84). One study

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[1] See Lindsay v. Ortho Pharmaceutical Corp., 481 F. Supp. 314, 350 (E.D.N.Y. 1979), 637 F. 2d 87 (2nd Cir. 1980).

showed the risk to be 15 or 20 times greater (R. 139). There were many other serious adverse reactions associated with the use of the pill (R. 85, 311, 313). Ortho was aware of these adverse reactions and the various studies that documented them (R. 83, 84).

Adverse reactions included thrombophlebitis, pulmonary embolism, cerebral thrombosis and hemorrhage, myocardial infarction, gallbladder disease, retinal thrombosis, optic neuritis, hepatic lesions with or without intra-abdominal bleeding, nausea, vomiting, gastrointestinal symptoms, breakthrough bleeding, spotting, change in menstrual flow, amenorrhea, edema, chioasma, melasma, cholastatic jaundice, migraine, rash (allergic), mental depression, change in weight, rise in blood pressure (R. 56, 85).

REASONS FOR DENYING THE WRIT

Assuming, arguendo, that a Federal question was timely and properly raised in the lower court, Ortho's petition does not present any special and important reasons for this Court to exercise its discretion to review on a Writ of Certiorari.

This Court has before it a reasoned and principled decision of the highest court of the Commonwealth of Massachusetts. The decision is firmly grounded on state common law, is supported by the record in all respects, and does not involve any denial of due process. Ortho has not come forward with any reason to justify this Court becoming involved in this litigation.

1. Petitioner Has Failed To Meet This Court's Stringent Standards For Review Of The Decision Of The Highest Court Of A State.

Rule 17.1 requires that there be "special and important reasons" amplified in argument in a Petition for Certiorari

(Rule 21.1(j)), before this Court will exercise its discretion to grant review. The Court has repeatedly emphasized that it has limited reviewing powers and that it does not sit for the benefit of particular litigants. *Rice* v. *Sioux City Memorial Park Cemetery, Inc.*, 349 U.S. 70, 74 (1955).

Ortho admits that "the lower court's extension of its state law may not in and of itself raise a substantial federal question," but suggests that some important question of Federal law is raised by the "irregular manner" in which the Court adopted the new rule of law (Pet. p. 17).

Ortho does not advance any valid argument as to why this Court should abandon its time-honored and common sense reluctance to entangle itself in a state court decision involving state law issues. The standards for review of alleged constitutional violations differ dramatically when the matter for review is the decision of the highest court of a state, as opposed to a lower federal court. Great deference is accorded to the highest court of a state in its resolution of both factual and state law issues.

> "The choice for any state may be determined by the juristic philosophy of the judges of her courts, their conceptions of law, its origin and nature. We review not the wisdom of their philosophies, but the legality of their acts."

Great Northern R. Co. v. *Sunburst Oil & Ref. Co.*, 287 U. S. 358, 365 (1932).

Even in cases where there may have been an error of state law in the case below, this Court has strictly adhered to the view that such an error simply does not provide the basis for a legitimate claim of a denial of due process.

> "We are not at liberty to conjecture that the trial court acted under an interpretation of the state law different from that which we might adopt and then set up our own interpretation as a basis for declaring that due process has been denied. We cannot treat a

> mere error of state law, if one occurred, as a denial of due process; otherwise, every erroneous decision by a state court on state law would come here as a federal constitutional question."

Gryger v. *Burke*, 334 U. S. 728, 731, reh'g denied, 335 U. S. 837 (1948).

Moreover, the Constitution simply does not guarantee that the decisions of a state court be free from error or that such decisions shall be consistent. *Patterson* v. *Colorado ex rel Atty. Gen.*, 205 U. S. 454, 461 (1906); *Worcester County Trust Co.* v. *Riley*, 302 U. S. 292, 299 (1937).

2. The Decision Of The Massachusetts Supreme Judicial Court Is Sound As A Matter Of State Common Law And Is Not Arbitrary And Unprincipled.

Faced with the obstacle of presenting a substantial federal question under this Court's standards for review of the decision of the highest court of a state, Ortho appears to resort to an attack upon the Massachusetts Court and its decision in this case.

Thus, Ortho accuses the Court of *inventing ab initio* judicial findings of fact (Pet. p. 2); of relying upon non-judicial facts *conceived* during the appellate process (Pet. p. 3); engaging in *ex parte* fact finding (Pet. p. 3) proceeding to *make up* peculiar characteristics of oral contraceptives (Pet. p. 5); adopting *fictive* findings of fact (Pet. p. 6); turning the appellate process into a *de novo* and *ex parte* fact finding inquiry (Pet. p. 7); and of adopting *unprincipled* findings, which can only spur other courts to do likewise (Pet. p. 13). Sprinkling Latin phrases and catch-words throughout the Petition, however, does not fulfill the requirement of presenting special and important reasons for granting review on certiorari.

According to Ortho, the Massachusetts decision is "startling" (Pet. p. 3) and "trailblazes" new law (Pet.

p. 6). In fact, the Court simply decided an unsettled issue of state law, as to the extent of the duty to warn owed by a manufacturer of oral contraceptives to a consumer. The court determined that under Massachusetts law, there is a duty to warn the consumer directly of risks inherent in the use of the product and that Ortho breached its duty in failing to warn Mrs. MacDonald of the risk of the "stroke," which she suffered as a result of taking Ortho's birth control pills.

The decision below is well-reasoned and was not rendered in a cursory manner. The Appellate Court had the case under advisement from May 8, 1984 (when oral arguments were presented) until February 28, 1985 (when its opinion was issued). See *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. 131 (1985).

In adopting its rule of law, the Massachusetts Court was free to reject the virtually unanimous rule elsewhere, that the prescription drug manufacturer must warn only the prescribing physician, not the patient. The Court engaged in a reasoned analysis of the rule and clearly scrutinized the reasons for it to determine whether its application was warranted in the case before it.

Although it recognized that the prescribing physician is a "learned intermediary" between the manufacturer and the patient, the Court established the necessity of a warning directly to the consumer in cases where, as here, oral contraceptives are prescribed. The rationale for the Court's decision is that oral contraceptives bear "peculiar characteristics" which set them apart from other prescription drugs. (See *MacDonald* v. *Ortho, supra,* 394 Mass. 136, 137).

The Court carefully delineated its reason for crafting an exception to the usual rule where oral contraceptives are involved. The distinctive nature of birth control pills was an issue raised in Mrs. MacDonald's appellate brief and in oral arguments presented to the Court, with ample data

to support the arguments. It is important to note that Mrs. MacDonald, like other healthy women, visited her physician, not because she was ill and desired that he prescribe a cure, but because she wanted to take the "pill" and needed a prescription in order to get it (R. 165).

In addition to considering analogous cases from other jurisdictions, the Massachusetts Court could and did consider scholarly treatises, the Restatement of the Law and germane law review articles. Faced with an unprecedented question of state law, a court may be guided by the law, which in its opinion, provides the most just and reasoned analysis. *Harrison* v. *McDonough Power Equipment, Inc.*, 381 F. Supp. 926, 930 (S.D. Fla. 1974).

The case does not, as Ortho contends, give rise to a "tremendous expansion of liability in prescription drug cases" (Pet. p. 3). The decision was limited to the failure to warn of "stroke" in cases involving oral contraceptives.

It is significant that Mrs. MacDonald suffered her stroke on July 24, 1976 (R. 153) and that, effective April 3, 1978, the FDA (by 43 Fed. Reg. 4221) amended its regulations to require that a birth control pill dispenser specify "stroke" as one of the potential serious side effects of the product.[2]

In compliance with the amended regulations, and for at least the past seven years, Ortho (and presumably, all other manufacturers of birth control pills) now provide a specific warning to the consumer of a risk of "stroke."[3]

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[2] See 21 C.F.R. § 310.501(a) 2 (iv) 1984.

[3] See *Lindsay* v. *Ortho Pharmaceutical Corp.*, 481 F. Supp. 314, 350 (E.D.N.Y. 1979).

3. The Massachusetts Decision Does Not Undermine FDA Regulations.

Dating back to at least 1970, the FDA recognized the necessity and feasibility of providing a direct warning to the consumer of the risks associated with birth control pills, and mandated the use of certain labelling in regard thereto.[4]

In 1976, when Mrs. MacDonald was stricken, oral contraceptives were the only prescription drug required to carry such a direct warning. (R. 286, 302, 305). Intrauterine devices and estrogen, progestational and isoproterenol products, which Ortho maintains are required by the FDA to carry a direct patient warning (Pet. p. 9 n. 2), did not become subject to such regulations until after 1976.

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[4] FDA regulations in effect during the time period relevant to this litigation required that the following warning be included in or with the dispenser:

> "DO NOT TAKE THIS DRUG WITHOUT YOUR DOCTOR'S CONTINUED SUPERVISION.
>
> "The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.
>
> "Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, (Firm name) has prepared a booklet (or other form) written in a style understandable to you as a drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet (or other form) if you ask for it and he can answer any questions you may have about the use of this drug.
>
> "Notify your doctor if you notice any unusual physical disturbance or discomfort."

21 C.F.R. § 130.45(d)(1), 35 Fed. Reg. 9002-9003 (1970), recodified at 21 C.F.R. § 310.501(a)(4), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5354 (1974).

Although it determined that for the "safe and effective use" of oral contraceptives, a direct patient warning was required (21 C.F.R. § 310.501(a)(1)), the FDA, in adopting its regulations, did not intend to preempt or define the bounds of the common law duty to warn. This is clear from the preamble to its 1978 regulations.[5]

Thus, the Massachusetts Court was warranted in concluding (with ample citations of authority) that the FDA regulation mandated only a minimal warning requirement and that the jury could have reasonably concluded that the warning to Mrs. MacDonald was inadequate, because it did not advise her of the risks of "stroke." (See *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. at 139, 140).

4. Ortho's Claim Of Denial Of Due Process Is Unfounded.

The gravamen of Ortho's Petition for Certiorari is that the Massachusetts Supreme Judicial Court denied it of due process because it allegedly engaged in "appellate fact-finding" and relied upon non-record evidence (Pet. p. 6).

Because we believe that the record is essential to a proper understanding of the case by this Court, counsel for the Respondents has requested the certification and transmission to this Court of the Appendix filed with the lower Appellate Court (Rule 19.1).

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[5] "The Commissioner does not agree that the imposition of a requirement for patient labeling will necessarily affect adversely the standard of civil tort liability which is imposed on drug manufacturers or dispensers. Whether or not a corporation or individual is to be held liable in a given situation will depend upon the facts surrounding the manufacture, sale, and use of the drug product, and on the nature of the injury. It will also depend on the applicable state law, which the Commissioner notes, can be adjusted by state courts and Legislatures in light of the facts presented by patient labeling."

43 Fed. Reg. 4214 (Jan. 31, 1978).

An examination of the record of the evidence presented at the trial of this case and reviewed by the Supreme Judicial Court on appeal rebuts Ortho's allegations that the Appellate Court "ma[de] up" peculiar characteristics of oral contraceptives without evidence "in the record or in the real world" (Pet. p. 5).

Contrary to Ortho's claim, the record contains ample evidence to support the lower court's conclusion that the oral contraceptive stands apart from other prescription drugs and requires a direct warning to the patient of the substantial risks affiliated with its use. (See *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. at 138.)

Evidence in the record to support this conclusion includes the following:

Patient involvement

Oral contraceptives are used for long periods of time by large numbers of women, who, for the most part are healthy and take them as a matter of choice for prophylaxis against pregnancy, in full knowledge of other means of contraception. (R. 80); 35 Fed. Reg. 9002 (1970).

Limited participation by prescribing physician

Mrs. MacDonald first received a prescription for birth control pills from her physician in 1973 and, thereafter, saw him for a yearly check-up, each time receiving a prescription for one year's supply of the pills (R. 144, 145).

The prescribed dosage is one tablet daily and the pills are available in bottles of 500 tablets (R. 56).

Extensive Federal regulations

Dating back to at least 1970, the FDA has published rules and regulations establishing labeling requirements for oral contraceptives (R. 79, 80, 81), 35 Fed. Reg. 9001, 9002, 9003 (1970).

Substantial risks affiliated with its use

A large number of adverse reactions were observed in patients (R. 56).

They are powerful drugs which can cause side effects. The most serious side effect is abnormal blood clotting which can be fatal (R. 57).

There is increased risk of thromboembolic disease, pulmonary embolism and cerebral vascular disease, associated with their use (R. 83, 84, 85).

People who use the pill are at a greater risk of thromboembolic disease, stroke being one of them, than the women who are not using the pill (R. 95).

Abnormal blood clotting and stroke are risks associated with the use of oral contraceptives (R. 101).

There is a positive association between the pill and stroke and with heart attacks and other diseases (R. 184).

The risk-factor for stroke for pill users as compared to non-users is as high as 20 times greater (R. 189).

No other drug has been written about as much in medical literature. (R. 298).

Feasibility of direct warning

Since 1970, the FDA has mandated a direct warning from the manufacturer to the purchaser of birth control pills (R. 80, 81).

In 1976, when Mrs. MacDonald suffered her stroke, oral contraceptives were the only prescription drug for which the FDA had mandated such a direct warnning (R. 286, 302, 303).

Possibility that oral communications between physicians and consumers may be insufficient

In determining the need for a direct warning, the FDA Commissioner concluded that

1. Many patients were not receiving the needed information in an organized, comprehensive, understandable and handy-for-future-reference form.

> 2. The necessary information for the safe and effective use of oral contraceptives is too complex to expect the patient to remember everything told her by the physician.
>
> The FDA was not provided assurance that persons for whom oral contraceptives are prescribed or dispensed were uniformly being provided the necessary information for safe and effective use of the drugs.
>
> Consumer spokesmen contended that there was ample evidence that physicians were not uniformly providing the information, and that when they do the patient cannot be expected to remember all of the details for a protracted period of time. (R. 80) 35 Fed. Reg. 9052 (1970).

Thus, it appears obvious that there is no basis for Ortho's contention that the State Court adopted a new rule of law on the basis of "fictive" findings of fact which Ortho was never allowed to test (Pet. p. 6).

* * *

The jury's award of $800,000.00 in damages to Mrs. MacDonald was intended as compensation to her for the permanent disability resulting from her stroke (R. 40, 41). The damage award was not punitive, nor is there anything in the record to suggest that the proceedings below were in any way discriminatory of Ortho or tended to make it a "scapegoat for public ire" as suggested. (Pet. p. 16, 17).

CONCLUSION

Ortho has had its day(s) in the Massachusetts Courts. No substantial Federal question has been raised by it, which should invoke the reviewing power of this Court.

For all of the reasons set forth above, this Petition for a Writ of Certiorari to the Supreme Judicial Court of Massachusetts should be denied.

Respectfully submitted,

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